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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/816,332

04/01/2004

Douglas Armand Demers

US030101

8770

28159 7590 06/14/2006

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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT

PAPER NUMBER

3768

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/816,332

Applicant(s)

DEMERS, DOUGLAS ARMAND

Examiner

Jaworski Francis J.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 11 are again rejected under 35 U.S.C. 102(b) as being anticipated in method and supporting structure by (a) Roundhill et al (US6447453) or (b) Yamauchi (US6730032) or (c) Olstad et al (US6447450) or (d) Schoisswohl et al (US6966878).

(a) Roundhill et al teaches a method for ultrasound imaging including collecting 3D volume segments as per col. 13 lines 12 – 49,,

[ The Examiner is applying a 'broadest reasonable interpretation' definition that 'volume segment(s)' for purposes of claim interpretation may pertain to a single volume unit (such as a scan plane as in the above-cited passage) or to a multi-planar subset of the complete scan volume, or to a complete such volume where it is contributing to a further average or other 4D activity that results in the eventual 'image data representative of a three-dimensional ultrasound image...'.]

and then Roundhill et al teaches further acquiring and displaying an ECG image<sup>12</sup> with marker 14, see col. 2 lines 39-56, concurrent with the aforementioned col. 13 passage-described volumetric buildup for display.

Such an ECG display as Fig. 15b tracing 12, 14 understood to display multiple heart cycle trace sets as in Fig. 1 suffices as meeting the comparative displaying step.

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[ Again a 'broadest reasonable interpretation' applies. If one were Web shopping for a car then a facility to display in a repeating format two vehicle feature sets side-by-side would be considered a comparative type display since the user is able to mentally complete a comparison without any favoring or disfavoring judgment exercised by the search engine.]

(b) Yamauchi et al may be analogously applied, with note that Yamauchi et al is directed inter alia to biplanar or orthogonal cross-section views and an active comparison is present in the machine (i.e. the latter Examiner note re language breadth need not apply) , namely image frame data re-alignment by machine comparison of ECG wavetrace slope using time-stamping is practiced in relation to a fixed cycle location for cardiac index determinations, see col. 4 lines 46-58, col. 7 lines 31-34, col. 17 lines 10-56.

c) Olstad et al uses ECG wavetrace registry in one aspect to obtain full 3D volume segments for cumulation into a 4D volume sequence using ECG display and machine comparison registry for time-stretching realignment, data discard or as a basis for spatial shift realignment between volume segments, see col. 7 lines 28-49, col.9 lines 55-63 and col. 10 lines 13 – 47.

(d) Schoisswohl et al is directed to assemblage of true multiplanar volume subsets termed 'series of adjacent scanplanes' as volume segments. Since Schoisswohl teaches that ECG is a way of getting a time-trace marker although not usual with the fetus (col. 1 lines 27-50, e.g. a fetal scalp electrode must be had, Exr's example) hence in the preferred embodiment an image-based fetal heart intensity trace is used,

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the Examiner is yet grouping the document as anticipatory in order to move the argument en bloc with further note that temporal comparisons are made using machine judgment in deriving a highest intensity zero reference marker and re-ordering volume segments in relation thereto, see also col. 7 lines 11 – 47.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 – 2, 11 are again further rejected under 35 U.S.C. 103(a) as being unpatentable over references (a) – (d), as argued above, and further in view of (i) Ubukata (US5813986), alone or further in view of Yamauchi(US6730032 for base references a),c),d)) or Inuma (US5551434) or (ii) Clark (US6139500), alone or further in view of Pang et al(US6558325).

(i) In an alternative argument if Roundhill et al or references (b) – (d) are considered to fall short as anticipatory regarding method and structure assuming arguendo some comparative use of the display must be explicitly stated, then it would have been obvious in view of either of the latter to also use displayed ecg data for comparison purposes in addition to display for uniformity observance. Specifically, in Ubukata Fig. 3 and col. 6 lines 7 – 37 describe a process in which the system comparatively judges based upon the displayed ECG whether the operator has

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accurately identified contraction or expansion phases for STI or ejection fraction determinations (this measurement purpose is also the case with Yamauchi). In Iinuma in contrast the system comparatively judges where the tomographic images are located temporally with respect to the acquired ECG sample point as a time registration benchmark for interpolation for time registry.

Alternately stated, during ultrasound imaging involving temporal assemblage of any of planar, orthogonal bi-planar, multi-planar or full volume segments a comparison may be going on based upon a displayed ECG trace or data of such a trace, which comparison is of a type unrelated to artifact elimination, specifically of a type related to electronic timing asynchrony with the ECG physiologic process..

(ii) In a further alternative argument with Roundhill et al or references (b) – (d) deemed as lacking ECG-based comparison, it would have been obvious in view of Clark (also directed to to time-scale for minor cycle-to-cycle ECG variations by comparative machine judgment with respect to a norm in order to perform time-scaling interpolation synthesize normal data intervals (col. 9 lines 21 – 29 and col.10 lines 1 – 43) or to re-acquire or interpolate over abnormal cardiac cycles (col. 5 lines 38-39).

In a further alternative under this argument (b) it would have been obvious in view of Pang et al as a generalizing teaching to provide comparative machine judgment for both system-physiology error and for interbeat physiologic error such that frame elements of a 3D volume being acquired are kept, expanded by interpolation or canned based upon evening out regional and temporal frame variations during 4D i.e. N-separate 3D volume acquisitions, and where the the cardiac cycle is gleaned from ECG

trace data (or from cardiocyclic image-based data) and a reference ideal ECG length is histogram-determined, see col. 4 lines 1-11 and 45 – 67, Fig. 7 and the attendant col. 7 – 8 discussion and col. 9 lines 34 – 40.

Alternately stated, during ultrasound imaging of the aforementioned various volume segment types a comparison may be going on based upon a displayed ECG trace or data of such a trace, which comparison is of a type related to artifact correction for physiologic aberrations.

. Claim 3-4, 12-13 are again rejected under 35 U.S.C. 103(a) as being unpatentable over any of references (a) – (d), alone or further in view of references associated with rejections I) or ii) above, further in view of Rowlandson (US6665559), alone or further in view of Harris et al (US3909792).. Whereas Roundhill et al as exemplary of method and supporting structure is silent as to 'separate ECG lines', Rowlandson merely serves to evidence that, when the ECG is acquired in association with ultrasound imaging (col. 2 bottom) it is often in a conventional 3-lead or 6-lead parallel format shown variously for 18, 100. Therefore it would have been obvious in Roundhill et al as exemplary to acquire multi-lead ECG waveforms across all traces and display these in parallel in order to assess the cardiac pathology whose diagnosis the concurrent ultrasound imaging is directed to achieving. The vertical line-up of the lead traces is 'visually distinctive' when an individual lead is referenced by the cardiologist. In the alternative, Harris et al directed to purely ECG technology evidences that it would

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have been obvious to distinguish an abnormal cardiac cycle ECG by both cursor and time-expansion highlighting.

Claims 5-6, 15 are again rejected under 35 U.S.C. 103(a) as being unpatentable over the references in their alternatives as applied to claims 4 and 12 above, and further in view of Warner et al (US6409659) since the latter would teach from the ECG art itself that colorized shadings may be used to indicate ECG abnormalities.

Claims 7, 16 are again rejected under 35 U.S.C. 103(a) as being unpatentable over the references in their alternatives as applied against claim 1, and further in view of Goldberg et al (US3951135) since the latter evidences that in one obvious variant of methodology and structure, when more than one line of ECG tracing is to be displayed it would have been obvious to under-write onto the next display line in non-aligned overlapping fashion.

Claim 8 is assigned claim 1 dependency as likenable to claim 7 in format however it is objected to for lacking a stated dependency; Claim 8 as well as claim 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references in their various alternatives as applied to claim 1 above, and further in view of Warner et al as representing colorizing method and apparatus, as the latter was applied above.

Claims 9 – 10 are again rejected under 35 U.S.C. 103(a) as being unpatentable over the references in their various alternatives as applied to claim 1 above, and further in view of Clark, since the latter suggests that flawed data associated with severe cardiac cycle aberrations should be discarded, reacquired or replaced with time-interpolated corrective image data.



Claim 17 is again rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 16 above, and further in view of Warner et al as the latter was applied regarding colorization supra.

### **Patentability Assessment/Response to Arguments**

ECG display over multiple cycles to represent physiologic cardiac timing is used in conjunction with ultrasound volumetric imaging where the volume unit being registered is the single scan plane as a volume segment (Roundhill et al) or dual scanplanes as a volume segment for the biplanar less-data-to-fool-with variant of 3D imaging (Yamauchi) or the multi-planar volume subset as volume segment (Schoisswohl et al) or the full volume set as volume segment for 4D accumulation of such segments (Olstad.) Therefore a base argument exists that the acquisition of volume segments of major categorizable types with wavetracing display of ECG cycles for operator comparison is known. Additionally, comparative machine judgment is exercised to temporally register these volume subunits against the innate misregistry tendency of the asynchrony between machine timing and heart cycle cadence, or against the variability of normal heart cycle cadence itself or abnormalities in this cadence, or against asynchrony due to both of these sources, with varying aspects of comparison such as in defining the average beat interval or defining the amount of registry or overage in uneven volume subset densities or logic decisions to alter keep, retake or discard image data, that is, data may be synthesized by time-shifting interpolation, or it may be kept as is, re-taken or discarded based upon these

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comparisons. At the same time, the ECG art apart from or only generally associated with ultrasound exam exhibits features associated with visually distinguishing abnormal heart wave runs including some colorized shading. Therefore the Examiner has assembled the details in support of this generalized line of argument in order to elicit exclusivity wordings in the claims, and an exhaustive reference-by-reference response to the resulting meshwork of rejections is not sought but rather the legitimate generalizing counterpoints to these details. Since applicant is merely claiming effectively an ECG trace display ongoing while at least the volume acquisition is going on, such was known in association with the references in order to assure for example that sufficient volumetric data was being gathered.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

6-12-06



Francis J. Jaworski  
Primary Examiner